(*1*) At least 6 semester hours were in inorganic chemistry and at least 3 semester hours were in other chemistry courses; and

(*2*) At least 12 semester hours in biology courses pertinent to the medical sciences; or

(B) *For those whose training was completed after September 14, 1963.*

(*1*) 16 semester hours in chemistry courses that included at least 6 semester hours in inorganic chemistry and that are acceptable toward a major in chemistry;

(*2*) 16 semester hours in biology courses that are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and

(*3*) 3 semester hours of mathematics; and

(ii) Has experience, training, or both, covering several fields of medical laboratory work of at least 1 year and of such quality as to provide him or her with education and training in medical technology equivalent to that described in paragraphs (b)(1) and (2) of this section; or

(5) With respect to individuals first qualifying before July 1, 1971, the technologist—

(i) Was performing the duties of a laboratory technologist at any time between July 1, 1961, and January 1, 1968, and

(ii) Has had at least 10 years of pertinent laboratory experience prior to January 1, 1968. (This required experience may be met by the substitution of education for experience); or

(6) Achieves a satisfactory grade in a proficiency examination approved by HHS.

[58 FR 39155, July 22, 1993]

§493.1495 Standard; Testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance and for reporting test results.

(a) Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

(b) Each individual performing high complexity testing must—

(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens;

(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

(4) Follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;

(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director;

(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications; and

(7) Except as specified in paragraph (c) of this section, if qualified under §493.1489(b)(5), perform high complexity testing only under the onsite, direct supervision of a general supervisor qualified under §493.1461.

(c) *Exception.* For individuals qualified under §493.1489(b)(5), who were performing high complexity testing on or before January 19, 1993, the requirements of paragraph (b)(7) of this section are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under §493.1461.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5236, Jan. 19, 1993; 60 FR 20050, Apr. 24, 1995]

Subparts N–P [Reserved]

Subpart Q—Inspection

SOURCE: 57 FR 7184, Feb. 28, 1992, unless otherwise noted.